

In re Application of: Andy Wolff et al  
Serial No.: 10/668,274  
Filed: September 24, 2003  
Office Action Mailing Date: January 17, 2008

Examiner: Elizabeth McNeill  
Group Art Unit: 3767  
Attorney Docket: 26486

**In the claims:**

1. (Previously presented) An oral device for controlled drug release, comprising:

a reservoir containing a drug;

an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of said subject.

2. (Original) The device of claim 1, wherein said electronic drug release mechanism further includes:

a control unit, for controlling said controlled release;

an electro-mechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and

a power source, for powering said control unit and electromechanical release mechanism.

3. (Original) The device of claim 2, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

4. (Original) The device of claim 1, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

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5. (Original) The device of claim 1, and further including at least one local sensor, integrated with said device.

6. (Original) The device of claim 5, and further including at least two local sensors, integrated with said device.

7. (Original) The device of claim 5, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

8. (Original) The device of claim 7, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

9. (Original) The device of claim 5, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

10. (Original) The device of claim 9, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.

11. (Original) The device of claim 1, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

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12. (Original) The device of claim 11, wherein said communication component provides communication with a personal extracorporeal system.

13. (Original) The device of claim 12, wherein said personal extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination thereof.

14. (Original) The device of claim 13, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

15. (Original) The device of claim 11, wherein said communication component provides communication with at least one remote sensor.

16. (Original) The device of claim 15, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, a temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

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17. (Original) The device of claim 1, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.

18. (Original) The device of claim 1, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

19. (Canceled)

20. (Original) The device of claim 1, wherein said drug is in nano-size particles.

21-24. (Canceled)

25. (Previously presented) The device of claim 1, wherein said device is adapted to be removably inserted to the oral cavity of the subject.

26. (Previously presented) The device of claim 1, wherein said device is adapted to be permanently inserted to the oral cavity of the subject.

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27. (Previously presented) The device of claim 1, wherein said device is adapted to be permanently inserted in the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.

28. (Previously presented) A method of controlled drug release, comprising:

providing an oral device for controlled drug release, which comprises:

a reservoir containing a drug;

an electronic drug release mechanism, configured for providing said controlled drug release into one or both of an oral cavity of a subject and an outer surface of an oral mucosa of a subject; and

an oral anchoring element, for configuring the oral device for insertion to an oral cavity of a subject; and

inserting said oral device to the oral cavity of a subject.

29. (Original) The method of claim 28, wherein said electronic drug release mechanism further includes: a control unit, for controlling said controlled release; an electromechanical release mechanism, which opens to allow the release of said drug, responsive to commands from said control unit; and a power source, for powering said control unit and electromechanical release mechanism.

30. (Original) The method of claim 29, wherein said control unit is selected from the group consisting of a dedicated electronic circuitry, a processor, an ASIC, and a microcomputer.

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31. (Original) The method of claim 28, wherein said device for controlled drug release further includes a timing device, selected from the group consisting of a timer, a clock, a calendar, and a combination thereof.

32. (Original) The method of claim 28, and further including at least one local sensor, integrated with said device.

33. (Original) The method of claim 32, and further including at least two local sensors, integrated with said device.

34. (Original) The method of claim 32, wherein said at least one local sensor is a physiological sensor, for drug release responsive to measurements of said sensor.

35. (Original) The method of claim 34, wherein said local physiological sensor is selected from the group consisting of a sensor for drug concentration in the saliva, a sensor for glucose concentration in the saliva, a sensor for a metabolite concentration in the saliva, a sensor for an electrolyte concentration in the saliva, a sensor for the pH level in the saliva, a sensor for the temperature in the oral cavity, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

36. (Original) The method of claim 32, wherein said at least one local sensor is a status sensor, for ensuring that the device is in proper operating condition.

37. (Original) The method of claim 36, wherein said local status sensor is selected from the group consisting of a sensor for remaining drug in the drug reservoir, a sensor for drug flow rate, a sensor for power source condition, and a sensor for short-circuit detection.

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38. (Original) The method of claim 28, and further including at least one communication component, selected from the group consisting of a receiver, a transmitter, and a transceiver.

39. (Original) The method of claim 38, wherein said communication component provides communication with a personal extracorporeal system.

40. (Original) The method of claim 39, wherein said personal extracorporeal system is selected from the group consisting of a remote control unit, a computer system, a telephone, a mobile phone, a palmtop, a PDA, a laptop, and a combination thereof.

41. (Original) The method of claim 40, wherein said personal extracorporeal system is adapted to provide communication between said device and a monitoring center.

42. (Original) The method of claim 38, wherein said communication component provides communication with at least one remote sensor.

43. (Original) The method of claim 42, wherein said remote sensor is selected from the group consisting of a sensor for drug concentration in the blood, a sensor for glucose concentration in the blood, a sensor for a metabolite concentration in the blood, a sensor for an electrolyte concentration in the blood, a sensor for oxygen level in the blood, a sensor for the pH level in the blood, a sensor for drug concentration in the interstitial fluid, a sensor for glucose concentration in the interstitial fluid, a sensor for a metabolite concentration in the interstitial fluid, a sensor for an electrolyte concentration in the interstitial fluid, a sensor for oxygen level in the interstitial fluid, a sensor for the pH level in the interstitial fluid, a sensor for drug concentration in the sweat, temperature sensor, a heartbeat sensor, a heart rate sensor, and a snoring sensor.

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44. (Original) The method of claim 28, wherein said device further includes at least one drug-transfer component for increased drug transfer through a biological barrier, by a process selected from the group consisting of iontophoresis, electroosmosis, electrophoresis, electroporation, sonophoresis, and ablation.

45. (Original) The method of claim 28, wherein said drug release mechanism provides said controlled drug release in a manner selected from the group consisting of release in accordance with a preprogrammed schedule, release at a controlled rate, delayed release, pulsatile release, chronotherapeutic release, closed-loop release, responsive to a sensor's input, release on demand from a personal extracorporeal system, release in accordance with a schedule specified by a personal extracorporeal system, release on demand from a monitoring center, via a personal extracorporeal system, and release in accordance with a schedule specified by a monitoring center, via a personal extracorporeal system.

46. (Canceled)

47. (Original) The method of claim 28, wherein said drug is in nano-size particles.

48-51. (Canceled)

52. (Original) The method of claim 28, wherein said device is adapted to be removably inserted to the oral cavity of the subject.

53. (Original) The method of claim 28, wherein said device is adapted to be permanently inserted to the oral cavity of the subject.



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54. (Previously presented) The method of claim 28, wherein said device is adapted to be permanently inserted in the oral cavity of the subject, and said device further includes a removable component, which houses at least one of said drug reservoir and said power source, said removable component being accessible without an invasive procedure.

55 - 110 (Canceled)

111. (Previously presented) The device of claim 1, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard.

112. (Previously presented) The method of claim 28, wherein said oral anchoring element is a dental implement, selected from the group consisting of a dental bridge, partial dentures, full dentures, braces, a molar band, a night guard, and a mouth guard.

113. (Previously presented) A method of releasing a drug into at least one of an oral cavity of a patient and an outer surface of an oral mucosa of a patient in a controlled manner, the method comprising:

- anchoring an electronic drug release mechanism to the outer surface of the oral mucosa of the patient, said electronic drug release mechanism
- controlling release of a drug from a drug reservoir; and
- activating said electronic drug release mechanism to release the drug in a controlled manner.

114. (New) An oral device for controlled drug release, comprising:  
a reservoir containing a drug;

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an electronic drug release mechanism, suitable for functioning at the conditions inside the oral cavity; and

an oral anchoring element, which anchors the oral device to oral tissue, to allow releasing the drug to the outer surface of oral mucosa.

115. (New) The oral device of claim 1, having a portion that faces a biting surface a tooth.

116. (New) The oral device of claim 1, comprising a hard outer shell.

117. (New) The oral device of claim 116, wherein said hard outer shell has at least one perforation for the drug release.